EXHIBIT A

GenBioPro, Inc.
P.O. Box 32011
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The Honorable Robert M. Califf, MD
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Building 32, Room 2346
Silver Spring, MD 20993-0002

March 1, 2023

Dear Commissioner Califf:

GenBioPro, Inc. ("GBP") is dedicated to ensuring that people have access to evidence-based, essential medications and, to that end, markets a generic version of Mifeprex (mifepristone) 200 mg consistent with FDA's regulatory regime. Given the external environment, I write to request prompt confirmation that any withdrawal of the approval of GBP's abbreviated new drug application ("ANDA") for mifepristone—whether by court order or otherwise—will follow all applicable procedures afforded by law and regulation to GBP as the ANDA holder and that FDA will permit GBP to continue marketing and selling mifepristone until those procedures have been completed.

GBP's ANDA (No. 091178) was approved by FDA on April 11, 2019, following almost a decade of efforts by GBP to bring the first and only generic version of Mifeprex (mifepristone) 200mg tablet to market. As you know, mifepristone 200 mg tablet is the first drug in a two-drug regimen approved by FDA for medication abortion. FDA's approval of GBP's ANDA reflects its judgment that this drug is safe and effective and was based on a robust review of vast amounts of data and hundreds of medical studies over more than two decades, including data submitted by GBP to support approval of its ANDA. FDA's decisions regarding mifepristone have twice been found to be legally and factually valid by the U.S. Government Accountability Office. *See* U.S. Gov't Accountability Off., *Approval and Oversight of the Drug Mifeprex* (Aug. 2008); U.S. Gov't Accountability Off., *Information on Mifeprex Labeling Changes and Ongoing Monitoring Efforts* (Mar. 2018).

Moreover, in the 2007 enactment of the Food and Drug Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823, Congress specified that, for 16 drugs that FDA had approved previously with "elements to assure safe use," Congress deemed them to have an effective Risk Evaluation and Mitigation Strategy (REMS) in effect. As to the set of drugs, including mifepristone, that have a REMS with elements to assure safe use, Congress mandated that any elements provide "safe access" for patients for the drug, and not be "unduly burdensome on patient access to the drug." 21 U.S.C. § 355-1(f). FDA thus regulates mifepristone under this congressional mandate, which requires safe access for patients. FDA most recently revised the REMS for mifepristone on January 3, 2023, after an extensive review of updated research and data.

Despite mifepristone's longstanding congressional and regulatory approval and despite widespread acknowledgment of the public health benefits of access to mifepristone, in the aftermath of the Supreme Court's decision last year in *Dobbs*, FDA's approvals have come under challenge and efforts are

underway to seek withdrawal of the approval for mifepristone. These ill-advised and unfounded attacks on FDA's decisions pursuant to its congressional mandate are of grave concern to GBP, which has invested considerable effort and expense in reliance on FDA's past regulatory actions with respect to mifepristone, as well as on FDA's well-established regulatory process for the withdrawal of existing drug approvals. Withdrawal of the mifepristone ANDA approval would threaten irreparable harm to both GBP as a company and the public interest, as expressed in the 2007 Amendments, in continued access to the medication.

As you are aware, in addition to mandating that FDA ensure safe access to mifepristone, Congress also granted FDA, and FDA alone, the authority to oversee the withdrawal of an approved drug application. See 21 U.S.C. § 355(e). Withdrawal requires a finding by FDA that one of the relevant statutory criteria has been met, as well as "due notice and opportunity for hearing to the applicant." Under the Food Drug and Cosmetic Act ("FDCA"), and as relevant here, the Secretary of HHS shall withdraw approval of an application if the Secretary finds that:

> clinical or other experience, tests or other scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which the application was approved . . . [or] on the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended or suggested in the labeling thereof.

21 U.S.C. § 355(e)(1), (3).

The Secretary, in turn, has delegated the responsibility for making such a finding to the FDA Commissioner. *See* FDA Staff Medical Guides, Staff Manual Guides 1410.10, *Delegations of Authority to the Commissioner of Food and Drugs* 1.A(1) (Nov. 29, 2022) (all functions vested in the Secretary under the FDCA are delegated to the Commissioner). Any withdrawal of a drug approval on safety or efficacy grounds therefore mandates that the Commissioner find that the evidence demonstrates that the drug's benefit-risk balance requires withdrawal. As the Supreme Court has emphasized, the statute does "not provide any mechanism other than the Commissioner's suspension authority under [section 355(e)], whereby an NDA once effective could cease to be effective." *See Weinberger v. Hynson, Wescott & Dunning, Inc.*, 412 U.S. 609, 633 (1973).

The regulations that implement section 355(e)'s requirements of notice and opportunity to be heard set out specific and detailed procedures the Agency must follow when analyzing withdrawal of a drug approval. In addition to notice and the opportunity for a hearing on a proposal to withdraw a drug, those regulations also expressly permit the applicant to submit studies, data and other information. *See* 21 C.F.R. §§ 314.150, 314.200, 314.530. Specifically with regard to the holder of an ANDA, like GBP, the regulations require an opportunity to submit written comments and, if a hearing is granted, the opportunity to participate and to submit written objections to an initial decision. *See* 21 C.F.R. §

314.151. The due process protections embodied within these statutory and regulatory procedures are constitutionally necessary for the protection of GBP's property interest in its mifepristone ANDA.[1]

Accordingly, GBP respectfully requests FDA's confirmation that for any FDA withdrawal of GBP's ANDA approval, including in response to a court order, FDA will initiate the statutory and regulatory procedures and apply the substantive criteria set forth above and that GBP would be permitted to continue to market and sell mifepristone in the United States while the established process for withdrawal of any approval for a drug process runs its lawful course.

Thank you for your consideration of this matter of pressing public importance. In light of the exigency of this matter, we respectfully request FDA's response as soon as practicable, but, in any event, no later than March 15, 2023. If you or your staff have questions, please do not hesitate to reach out.

Sincerely,

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CC:
Hon. Xavier Becerra
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[1] Moreover, and importantly, if the reference drug in GBP's ANDA is required to be withdrawn for reasons *other than FDA's determination that the reference drug is unsafe or ineffective for use under the conditions set forth in its application*, that should have no impact on GBP's ANDA for mifepristone. *See* 21 U.S.C § 355(j)(6).